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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/994,444

11/27/2001

Elizabeth Esther Mary Bates

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05/03/2005

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/994,444

Applicant(s)

BATES ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

1. Applicant's remarks filed 1/31/05, are acknowledged.
2. Claims 20-27 are pending and being acted upon.
3. 35 U.S.C. 101 reads as follows:  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claims 20-27 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

As set forth previously, the instant claims are drawn to a polynucleotide encoding the polypeptide referred to as A07C03 (SEQ ID NO:8). The specification asserts at page 18 that the claimed polynucleotides are useful "to isolate genes from other species". The protein encoded by the claimed polynucleotide is asserted to be useful "for generating antibodies." The antibodies could then be useful for screening expression libraries. Clearly, what the specification discloses is that the claimed invention is useful essentially for studying itself. Said study is not considered to be a specific and substantial asserted utility or a well-established utility. At page 59, the specification discloses that the claimed "DNA or RNA may be used as a component in a forensic assay," however, no specific assays are disclosed. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility. Therapeutically, the specification discloses that the protein encoded by the claimed polynucleotide "may be useful in the treatment of conditions associated with abnormal physiology or development, including abnormal proliferation, e.g., cancerous conditions, or degenerative conditions." However, no correlation or connection between the polynucleotides of the instant claims, nor the proteins they might encode, with any "abnormal physiology" or conditions is established. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility.

Applicant's arguments, filed 1/31/05, have been fully considered but they are not persuasive. Applicant argues that A07C03 is dendritic cell (DC) specific, thus, the polynucleotides can be used as markers for dendritic cells. Applicant has submitted four references expounding the value of DC-specific markers. Applicant argues that no DC-specific markers exist even today.

It remains the Examiner's position that the specification does not provide a substantial asserted utility or a well-established utility for the polynucleotide of the instant claims. While DC-specific markers may or may not comprise a certain value, the specification discloses that A07C03 is not a

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DC-specific marker because it also labels monocytes. Monocytes are not DCs. And, as set forth previously, the specification does not even actually reveal how the polynucleotide was isolated, or from what source. While not required, such a disclosure might have been helpful in establishing utility. Curiously, the specification does disclose that a mouse "counterpart" (EST W55567) was isolated from brain (not a likely source of DCs).

Regarding Applicant's argument that no DC-specific markers exist even today, several DC-specific cell markers are known, e.g., CD83, DC-SIGN, etc. Accordingly, Applicant's arguments regarding the value of the polynucleotide of the instant claims have not been found convincing.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-27 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

See Applicant's arguments and the Examiner's response of part 4 above.

7. Claims 20 and 25-27 stand rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed (note that the new matter portion of the claims is underlined), specifically:

A) In Claim 20, a polynucleotide encoding a polypeptide

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comprising amino acids 1-219 of SEQ ID NO: 8.

Applicant's arguments, filed 8/09/04, have been fully considered but they are not persuasive. Applicant argues that support for A) can be found in the mature A07C03 polypeptide of Table 2

Regarding A), first, it is well-established that polypeptides do not render obvious all of the polynucleotides that might encode them. Second, it is noted that the Table 2 legend discloses no "mature" polypeptides and actually discloses that the signal sequence (that would be removed from the mature polypeptide runs from about -22 to about -1, thus, not actually defining even the signal sequence.

Applicant has not addressed this rejection in the instant remarks.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.


11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact

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the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

  
4/21/08

G.R. Ewoldt, Ph.D.  
Primary Examiner  
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